



Members of the Appropriations Committee:

We are here to discuss a needed addition to HB H.B. No. 5037 (COMM) AN ACT ADJUSTING THE STATE BUDGET FOR THE BIENNIUM ENDING JUNE 30, 2023.

I am Angie Gochenaur, Director of State Government Affairs for Pear Therapeutics. Thank you for allowing me to testify as Connecticut needs all the resources available for doctors in their treatment plan for OUD and SUD.

Pear Therapeutics CT Public Testimony

The substance use opioid epidemic has highlighted the need for wider access to pharmacological and behavioral treatments for substance use disorders (SUD), and this has been exacerbated in CT during the COVID-19 crisis. For patients suffering from substance use disorder due to cocaine, cannabis and stimulants (such as methamphetamine) there are no FDA-approved medications, and contingency management is one of the few evidence-based practices that has demonstrated improvement in outcomes in patients with use disorders to these substances. Given the majority of patients (90%) do not receive the necessary/required behavioral treatment there is an urgent need for novel approaches¹³.

Prescription digital therapeutics (PDTs) deliver clinically validated disease treatments via mobile devices and can mitigate many treatment barriers by offering accessible and consistent evidence-based treatments, available to patients 24/7. Specifically, the 2 first FDA Authorized PDTs (reSET® and reSET-O®), available in both English and Spanish include as part of their three mechanisms of action: addiction-specific cognitive behavioral therapy, fluency training, and contingency management delivery of contingency management to treat substance use disorder and Opioid Use Disorder, respectively.^{1,2}

The clinical evidence supporting reSET® and reSET-O® as PDTs for SUD and opioid use disorder (OUD) is as follows- reSET® and reSET-O® are PDTs that provide cognitive behavioral therapy (CBT) as an adjunct to a contingency management system for adult patients in outpatient treatment under the supervision of a clinician^{1,2}. Behavioral therapy lessons are modeled on the Community Reinforcement Approach which is a specific form of CBT designed for patients with SUD. Contingency Management is an evidence-based behavioral therapy for the treatment of substance abuse in which patients are rewarded for adherence to their treatment plan.

Contingency management is one of the most efficacious interventions to support patients in their reduction of substance use, their retention in treatment and movement into recovery. Since the early 1970s, hundreds of experimental studies and randomized controlled trials (RCTs) have demonstrated the effectiveness and versatility of contingency management (CM) interventions^{3,4}. Several systematic reviews have concluded that CM is effective in the treatment of substance-use disorders^{5,6,7}, CM is one of the most rigorously tested and broadly successful application of behavior analytic principles in randomized controlled trials⁸. While the federal agency, Substance Abuse and Mental Health Services Administration (SAMHSA), recommends contingency management as an evidence-based practice, and the American Society of Addiction Medicine (ASAM) strongly recommends Contingency Management as a component of behavioral treatment, many patients who could benefit are unable to get access^{15 16}.

reSET® is indicated as a 12-week prescription only treatment for patients with SUD, who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or who do not abuse opioids as their primary substance of abuse¹. reSET® is intended to increase abstinence from a patient's substances of abuse during treatment and increase retention in the outpatient treatment program. The therapeutic content of reSET® was validated in a pivotal, randomized clinical trial¹ of 399 patients seeking treatment for SUD in ten nationwide community treatment programs. Patients were randomized to either treatment as usual (TAU) consistent with intensive outpatient treatment, or reduced TAU and reSET®. Patients treated with reSET® (n=206) had higher rates of abstinence in the final 4 weeks of treatment (40.3%)

than those in TAU (17.6%; n=193; p=0.0004). There was also increased treatment retention at the end of the 12-week study in the reSET® group (76.2%) compared to TAU (63.2%; p=0.0042). reSET® did not demonstrate a significant difference in unanticipated adverse events.

Advances in digital and behavioral technology may increase access and cost effectiveness and may further optimize technology-based CM. Digital tools permit remote reporting of substance use, but also remote delivery of incentives and provide new ways to deliver contingency management to promote abstinence from substance use. One barrier to PDT treatment is access. Innovations in digital and information technology may permit unprecedented access to some forms of CM treatment. Over the past 14 years, technology-based CM has been applied successfully to a range of problem health behavior such as cigarette smoking, alcohol misuse, physical inactivity, and medication nonadherence^{9,10}.

reSET-O® is intended to increase retention of patients with OUD as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for adults patients currently under the supervision of a clinician^{2 14}. The pivotal trial of reSET-O® randomized 170 adults with OUD to treatment as usual (TAU: buprenorphine maintenance therapy plus contingency management) or TAU plus the digital therapeutic for 12 weeks^{2 14}. 82% of patients in the reSET-O® group (n=91) stayed in treatment vs. 68% of those in the TAU group (n=79), and this was significantly different (p=0.0224). The AEs observed were not adjudicated to be device related.

A real-world observational study evaluated reSET-O® in 3,144 individuals with OUD. 80% completed at least 8 of 67 possible therapeutic modules, 66% completed half of all modules, and 49% completed all modules.¹¹ 74.2% of patients were retained through the last 4 weeks of treatment. A recent claims data analysis of the first reSET-O®-treated patients (n=351; 82.6% Medicaid enrollees) showed a 33% reduction in the incidence of all-cause inpatient stays, emergency department visits, partial hospitalizations, and inpatient observation events, in the six months post-reSET-O® initiation vs. the six months prior to reSET-O® initiation (IRR:0.67; p<0.05).¹² Concomitant decreases in clinician services were observed although there was an 8% increase in case management services. The reduction in hospital and medical services utilization, coupled with an increase in case management services (indicative of greater engagement with recovery services) is in line with previous independent observations. Together with the robust pivotal data, the RWE data support the engagement and clinically meaningful outcomes associated with PDTs in this difficult to treat population.

Currently reSET and reSET-O are preferred on the MassHealth non-drug formulary with no PA. We have requested CT Medicaid to mirror coverage like MassHealth given the high need in CT for more evidence-based treatments for Substance and Opioid Use Disorders. Currently some employers in the CT private sector (The Hartford, Prime Therapeutics) offer commercial coverage for reSET and reSET-O but citizens in the Medicaid program are not able to access these treatments. CMS has recently designated unique HCPCS code A9291 Prescription digital behavioral therapy, FDA cleared, per course of treatment. This allows Payors, including Medicaid, to cover PDTs via the pharmacy (NDC Code) or DME (medical/HCPCS Code A9291) benefit.

The state of Michigan recently appropriated \$1.5 Million of federal state opioid response grant funding to develop a pilot program integrating innovative prescription digital therapeutics to assist individuals with opioid use disorder with recovery. The pilot program integrating innovative prescription digital therapeutics will use evidence-based technologies modeled on a specific form of cognitive behavioral therapy combined with fluency training in conjunction with contingency management for opioid use disorders, known as community reinforcement approach.

We are asking this committee to:

Request coverage under Medicaid for PDTs for OUD and SUD and, or
Grant a budget line item to be used by CT Medicaid to develop a pilot program integrating innovative prescription digital therapeutics to help people in CT with substance use disorder or opioid use disorder on their recovery journey.

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